SEP 12 2012

510(k) Summary
CS Orthodontic Imaging and CS OMS Imaging software

1. Company Identification

Carestream Dental LLC
1765 The Exchange
Atlanta, GA 30339
Establishment Registration 1226003
Owner/Operator: Carestream Health, Inc.
Owner/Operator Registration: 9097221

2. Contact Person

Daniel Hoefer
Manager, Regulatory Affairs, Carestream Dental
1765 The Exchange
Atlanta, GA 30339
Tel 770 226 3287
Fax 770 850 5011

3. Device Name

Commercial name:	*CS Orthodontic Imaging, CS OMS Imaging*
Common name:	Dental Imaging Software
Classification name:	System, Image Processing, Radiological

4. Device Classification

Class: II, 21 CFR 892.2050
Product Code: LLZ

5. Intended Use

CS Orthodontic Imaging and CS OMS Imaging software is intended for use by orthodontists, oral surgeons, and their clinical staffs in storing and organizing images, including digital photographs, x-rays, and others. The system includes the capability to trace a cephalometric x-ray, analyze the measurements taken, and make growth or surgical predictions.

6. Device Description

CS Orthodontic Imaging and CS OMS Imaging software is a modification of currently legally marketed Kodak Orthodontic and OMS Imaging v8.0 software (K043104). The software is intended for installation at orthodontic or oral surgery clinics and offices on general purpose off-the-shelf computers systems (PCs) running Microsoft Windows in a peer-to-peer network.

Both the modified and unmodified devices consist of imaging software for orthodontic and oral surgery practices. The software provides the ability to connect satellite offices and may be marketed as a base system, with additional modules offered as options. The base system includes the storage, annotation and display of images. The optional Analysis module enables the user to trace the cephalometric x-rays using standard analyses. The optional Planner module enables the user to simulate orthodontic or surgical treatment in order to communicate treatment objectives or demonstrate and explain potential surgery to the patient.

When used with Carestream's panoramic, cephalometric, and other imaging systems, the device provides an interface that enables the practitioner to acquire radiographic images of the dentomaxillofacial region. The software then allows the user to visualize anatomical structures through the use of a computer display and store the information electronically in a clinical software program. CS Orthodontic and OMS Imaging software includes records of hard and softcopy charts, treatment plans, clinical notes, and clinical exam data. The software also enables the user to retrieve an electronic copy of an x-ray image from other imaging systems.

The device includes options for image viewing or presentation, including thumbnail viewing, single image viewing, and merging images into a letter (i.e., as part of a written communication to the patient). The image manipulation options include grayscale, invert, emboss, brightness, contrast, gamma, sharpen, median, d-speckle, hue, saturation, equalize, flip, mirror, masking, and rotate functions. Image annotation functions allow the user to add text to images, to measure distances and angles, magnify images, and other functions.

CS Orthodontic and OMS Imaging software can be integrated with Carestream's dental and dental sub-specialty practice management system software or used as a stand-alone product.

7. Substantial Equivalence

CS Orthodontic Imaging software and CS OMS Imaging software is substantially equivalent to Kodak Orthodontic and OMS Imaging 8.0 (K043104). See comparison table below (pages 3-4).

8. Non-Clinical testing

Verification and validation testing of the CS Orthodontic Imaging and CS OMS Imaging software has been performed, including verification of all specified software and hardware interfaces. Results of testing demonstrate that the device is safe and effective in meeting user requirements in accordance with its intended use.

9. Conclusion

CS Orthodontic Imaging and CS OMS Imaging software is substantially equivalent to Kodak Orthodontic and OMS Imaging 8.0, the predicate device listed above.

Comparison Table

Characteristic	Kodak Orthodontic and OMS Imaging 8.0	CS Orthodontic and OMS Imaging v11.0
510(k) number	K043104	pending
Manufacturer	PracticeWorks Systems, LLC	Carestream Dental LLC (formerly PracticeWorks Systems, LLC)
Branding	Kodak	CS
Indications for use	Indicated for Use by Orthodontists and clinical staff for storing and organizing digital images, including digital photographs and x rays. The device includes the capability to trace digital cephalometric radiographs, analyze measurements taken, and make growth projections	Indicated for Use by Orthodontists and clinical staff for storing and organizing digital images, including digital photographs and x rays. The device includes the capability to trace digital cephalometric radiographs, analyze measurements taken, and make growth projections
Platform	IBM-compatible PC or PC network	Same
Operating System	Microsoft Windows	Same
User Interface	Mouse, Keyboard	Mouse, Keyboard
Image Input Sources	Images can be scanned, loaded from scanners, digital cameras or card readers, or imported from a radiographic imaging device.	Images can be scanned, loaded from digital cameras or card readers, or imported from a radiographic imaging device.
32-bit software	Yes	Yes
Image formats	Multiple, including DICOM	Multiple, including DICOM
Patient Database Compatibility	Access	SQL
User Functions		
Characteristic	**Kodak Orthodontic and OMS Imaging 8.0**	**CS Orthodontic and OMS Imaging v11.0**
Includes Image measurement tools	Yes (linear distance, angle)	Yes (linear distance, angle)
Interface with Carestream imaging devices	Image acquisition from: • Kodak 8000 panoramic imaging system, Kodak 8000C pan/ceph, • RVG 6000 intraoral sensor, • Kodak 1000 Intraoral camera	Image acquisition from: • Kodak 8000 panoramic imaging system, Kodak 8000C pan/ceph, • Kodak 9000/9000C/9000 3D • Kodak 9500 3d Imaging system, • CS 9300/9300C 3d imaging system • RVG 6000, RVG 5000, RVG 6100, RVG 5100, and RVG 6500 intraoral sensors • Kodak 1000, Kodak 1500 • CR 7400 Dental computed

		radiography systems
Image viewing	Full, side-by-side, gallery, thumbnail	Full, side-by-side, gallery, thumbnail, filmstrip
Image manipulation	grayscale, invert, emboss, brightness, contrast, gamma, sharpen, median, despeckle, hue, saturation, equalize, flip, mirror, masking, rotate, annotation, cephalometric tracing, ceph growth projections, implant simulations	Same
Cephalometric Tracing	In addition to user-configured analysis, standard orthodontic tracing analyses include: • Downs • Jarabek • McNamara • Ricketts • Roth • Sassouni • Steiner • Tweed	Same
Growth projections	Simulated Growth projections on lateral photos used for patient communication	Same
Implant module	Simulates Generic implants only	Include implant libraries from Nobel Biocare, Bicon, 3i, and Straumann, and generic.
3D imaging capabilities	None	None. Includes interface to 3D imaging software provided with Kodak 9000, Kodak 9500, or CS 9300 systems. CS Orthodontic and OMS Imaging software does not view, transfer or process 3D radiographs.
Image Annotation	Text, paint, ellipse, pointer, select, draw, magnify, line, rectangle, polygon, ruler, protractor, smile library, smudge, brush	Text, paint, ellipse, pointer, select, draw, magnify, line, rectangle, polygon, ruler, protractor, smile library, smudge, brush, redeye reduction, select region, copy/paste

DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room – WO66-G609
Silver Spring, MD 20993-0002

SEP 12 2012

Mr. Daniel Hoefer
Manager, Regulatory Affairs
Carestream Dental LLC
1765 The Exchange
ATLANTA GA 30339

Re: K122427
Trade/Device Name: CS Orthodontic Imaging and CS OMS Imaging software
Regulation Number: 21 CFR 892.2050
Regulation Name: Picture archiving and communications system
Regulatory Class: II
Product Code: LLZ
Dated: August 7, 2012
Received: August 10, 2012

Dear Mr. Hoefer:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into class II (Special Controls), it may be subject to such additional controls. Existing major regulations affecting your device can be found in Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Parts 801 and 809); medical device reporting (reporting of

medical device-related adverse events) (21 CFR 803); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820). This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Parts 801 and 809), please contact the Office of *In Vitro* Diagnostic Device Evaluation and Safety at (301) 796-5450. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely Yours,

Janine M. Morris
Director
Division of Radiological Devices
Office of In Vitro Diagnostic Device
Evaluation and Safety
Center for Devices and Radiological Health

Enclosure

K122427

Indications for Use

CS Orthodontic Imaging and CS OMS Imaging software is indicated for use by orthodontists or oral maxillofacial surgeons and their clinical staff in storing and organizing images, including digital photographs and x-rays. The device includes the capability to trace a digital cephalometric radiograph, analyze the measurements taken and make growth or surgical predictions.

Concurrence of CDRH, Office of Device Evaluation

Prescription Use X OR Over-The-Counter
(Per 21 CFR 801.109)

(Division Sign-Off)
Division of Radiological Devices
510k K122427